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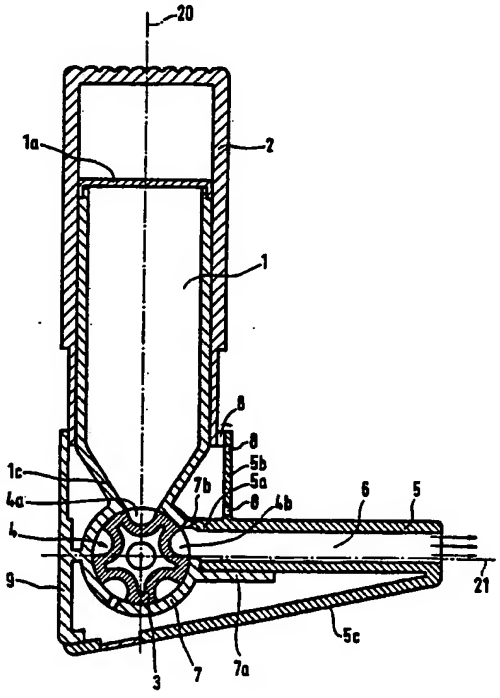
(54) Title: INHALATION DEVICE

(57) Abstract

The invention relates to a propellant-free inhalation device with a supply of pulverized medical substance in a supply chamber, which has a rotatable dosing means (3) with one or more dosing chambers (4) to receive in one defined position the dose of the medical substance to be inhaled from the supply chamber and to discharge the dose in another position. The inhalation device further is provided with a mouthpiece for active inhalation and an air channel (76) to distribute the dose discharged from the dosing chamber in the flow of breathing air.



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INHALATION DEVICE

This invention relates to an inhalation device. A propellant-free inhalation device with a supply of pulverized medical substance in a supply chamber, a manually actuatable metered dosing means in form of a rotatable dosing means having one or more peripheral recesses (dosing chambers) to receive in one position from the supply chamber the dose of the medical substance to be inhaled and to discharge the dose in another position, with a mouthpiece, formed at the side of the housing of the inhalation device for active inhalation and with an air channel for distributing the discharged dose in the breathing air flow and with at least one air intake embodied within the housing is described in DE 35 35 561.

In the known inhalation device the mouthpiece is arranged in such a way that its axis extends parallel to the axis of the dosing means. Its air channel is guided underneath the dosing means to the opposite side of the housing where the air intakes are situated, by forming a cavity on the level of the dosing chamber. If due to a rotation of the dosing means the loaded recess (dosing chamber) is facing the air channel of the mouthpiece, the dose of powder that has been before discharged from the supply chamber falls, due to the gravity forces and - if desired - supported by a vibrating mechanism from the dosing chamber into the cavity of the air channel and is therefrom inhaled into the lungs of the patient by means of active inhalation. The air channel has a throttle area which is destined to promote the mixing of air with the medical substance by means of turbulence.

The known inhalation device has two critical drawbacks. On one hand the accuracy in dosing the powder to be inhaled and in emptying the dosing chambers is not satisfactory, on the other hand a reliable dispersion of the powder in the breathing air is not warranted. For proper handling of the known device both hands are necessary. Emptying of the dosing chamber and getting all the powder out of the mouthpiece is not guaranteed.

It is the object of the present invention to construct an inhalation device, starting from the above mentioned propellant-free inhalation device, in which the inhaled dose is reproducible at a high level of accuracy and in which a complete dispersion of the medical substance into the breathing air is achievable.

This object is achieved according to the invention by the following features: The main axis of the mouthpiece and the axis of the dosing means form an angle in the range of 70 to 110°, preferably 90°. The air channel is led on the level of the dosing means directly to the periphery of the dosing means, offset from the outlet of the supply chamber. The air intake is formed at the attachment area of the mouthpiece and is extended to the periphery of the dosing means in the orifice area of the air channel.

In the propellant-free inhalation device of the invention the air intakes are therefore arranged in such a way, respectively the paths of the air ducts are chosen such, that immediately at the beginning of the inhalation process air is led directly into the filled dosing chamber of the dosing means and that the same is intensively flushed by the inflowing air. The sucked-in air therefore blows the

dosing chamber clean. Because of the relatively short air path between dosing chamber and the orifice of the mouthpiece the blown-out dose is received by the patient nearly completely. The actually inhaled dose therefore is reproducible at a high level or accuracy in the propellant-free inhalation device of the invention; also a complete dispersion of the medical substance in the air stream is achieved.

In a feature of the embodiment the dosing means is received in a fixed hollow cylindrical body which has recesses corresponding to the width of the dosing chambers and being spaced apart on the circumference of the dosing means according to the angular distance of the dosing chambers, said recesses being located on one side in the area of the supply chamber and on the other side in the area where the air channel of the mouthpiece and the air intake discharge into the cylindrical body.

Such an embodiment creates a clear separation, free of retroactions, between the receipt of the dose to be inhaled from the supply chamber on the one hand and the discharge of the dose to be inhaled into the air channel of the mouthpiece on the other hand.

Preferably, between the recess associated with the mouthpiece and a wall portion of the air channel of the mouthpiece, there is provided an opening for the passage of the intaken air directly at the periphery of the dosing means. An especially intensive air jet for cleaning off the dosing chamber positioned in front of the gap results when the gap is moulded like a nozzle.

Therapeutical preparations for inhalation often consist of a micronized drug and a less finely divided auxiliary substance which together form agglomerates (DE-A-1792207). Agglomerates are, however, also formed if the preparation only consists of uniformly micronized particles. Only the individual particles of the drug shall reach the deeper areas of the patient's lung. Therefore already in the mouthpiece of the device a separation of auxiliary substance and drug particles and desagglomeration (dispersion) should take place. For this purpose as high shear forces as possible should act on the agglomerates thus helping to disperse the particles adhering to each other. So according to another feature of the embodiment the cross-sectional shape of the air channel in the mouthpiece is adapted to create high shear forces.

This can be achieved, for example, if the air channel in the mouthpiece has a substantially constant cross-sectional area.

Other features and advantages of the invention will become apparent from the description of the examples shown in the drawings.

Fig. 1 is a longitudinal section through one embodiment of the inhalation device according to the present invention;

Fig. 2 is an explosive view of the structure of the inhalation device according to Fig. 1 in connection with other variants of parts of the device;

Fig. 3 is a cross section of a modified dosing means of the inhalation device;

Fig. 4 is a cross section of another modified dosing means.

Fig. 1 shows a propellant-free inhalation device with a supply chamber 1 into which a certain supply of a pulverized medical substance to be inhaled is filled. As a rule, the amount is measured that it is sufficient for up to 300 single doses.

The supply chamber has a square cross-section (Fig. 2) and a lid 1a is tapered towards the bottom. A long extending cover 2 is put onto the supply chamber 1.

At the end of the conical portion 1c of the supply chamber there is a manually actuatable dosing means 3 having five peripheral recesses 4, called dosing chambers. In the position of the dosing means shown in Fig. 1, the upper dosing chamber 4a is just being filled with the dose of medical substance to be inhaled from the supply chamber 1, while the earlier filled dosing chamber 4b is ready to be discharged.

At one side of the inhalation device a mouthpiece 5 is formed, through which the medical substance can be inhaled actively and which has an air channel 6 for distribution of the dose discharged from the dosing chamber 4b into the flow of breathing air. In the example illustrated, the main axis 21 of the mouthpiece 5 forms an angle of approxemately 90° with the axis of the dosing means 3. The embodiment of the invention, however, in no way is restricted to this form. Angles of approx. 70° to 110° can likewise be formed. The longitudinal axis of the mentioned air channel in the example is therefore perpendicular to the longitudinal axis of the dosing means. In the vicinity of the dosing means the air

channel is led at the level of the dosing means directly to its periphery. According to the position shown in Fig. 1 the air channel is thus directly opposite the dosing means, here the dosing chamber 4b.

The dosing means is received in a fixed hollow cylindrical body 7 which has recesses corresponding to the width of the dosing chamber 4, set off on the circumference by the angular distance of the dosing chambers 4a and 4b, the recesses being located on the one side in the area of the conical section 1c of the supply chamber and on the other side in the area where the air channel 6 of the mouthpiece 5 discharges.

In the area where the mouthpiece is attached, air intakes 8 are provided. The intaken air is led to an opening 7b between the recess of the hollow cylindrical body that is facing the mouthpiece and a partition wall 5a of the mouthpiece. From the opening the air arrives directly like a jet in the dosing chamber 4b and blows the powder contained therein out into the air channel 6 of the mouthpiece 5, without leaving any residue. It is preferred to mould the mentioned air supply opening 7b like a nozzle to create a strongly aligned stream of air.

In Fig. 2 the structure of the inhalation device according to fig. 1 is made clear in an explosive view.

The cover 2, together with the flap 2a, the function of which will be explained further below, is adapted to cover the supply chamber 1 and its lid 1a. Said lid closes the upper edge of the supply chamber.

An integral connection is provided between the supply chamber 1 and the hollow cylindrical body 7, which is adapted to mount the dosing means 3 with the dosing chambers 4. Moulded together with the supply chamber is also the rear wall 9 of the device, likewise the attachment 7a to receive the mouthpiece 5 including the wall 5b with the air intakes 8 and the air channel 6 as well as the bottom side 5c of the device (fig. 1).

In addition to the dosing chambers 4, the dosing means 3 also has teeth 3a which are engaged with the flap 2a such that rotation can only be accomplished stepwise corresponding to the peripheral distance between the dosing chambers 4 and the recesses in the body 7 (fig. 1). The detent drive of the dosing means automatically aligns the dosing chambers with the outlet of the supply chamber on the one side and the air channel of the mouthpiece on the other side. Thus a good charging and discharging of the dosing chamber is ensured. Furthermore, the supply chamber 1 has a detent nose 1b which engages into recesses or notches 3b in the dosing means such that analogue to a ratchet rotation is only possible in one direction. It is thus possible to actuate the device just as the usual metered dose inhalers containing propellants.

To reduce friction between the dosing means 3 and the cyclindrical body 7 different shapes and sizes of the slot 7c can be formed.

The mouthpiece can be closed with a cover 10 which comprises detent noses 11 to engage into the air intakes 8 and subsequently close the same and take care of a safe sealing of the device. Furthermore, an unintended operation is prevented.

In another embodiment the cover 10 is connected to the mouthpiece or to the device so that it can be pulled off the mouthpiece, but cannot be completely removed from the device.

In another form of embodiment according to Fig. 1 the lid 1a of the supply chamber 1 for the medical substance may comprise a chamber, which, for example, is filled with silicagel or another drying agent to protect the medical substance against humidity.

Furthermore a vibrating mechanism can be provided, by means of which the medical substance is shaked when the device is operated, so that the respective dosing chamber receives a uniform charge. This vibrating mechanism, for example, can be formed by a ratchet in a manner known per se. The supply chamber 1 or the cover 2 can also have notches, which cause vibrations when these parts are moved relatively to each other.

Also for the design of the drive of the dosing means the man skilled in the art avails of several possibilities. In the simplest case this design can be embodied corresponding to the dosing devices in aerosol systems. Preferrably the drive is adapted to be rotated manually by means of a knob.

Also with respect to the detent drive and the "ratchet" other embodiments are imaginable.

The inhalation device desirably includes an arrangement, which prevents multiple doses to be discharged from the device.

The opening at the conical portion 1c of the supply chamber 1 is shaped for low friction forces of the dosing means in its bearing and easy rotation of the barrel without jamming.

For visual monitoring of the supply level in the supply chamber the supply chamber preferably is manufactured of usual transparent material. In the cover 2 a longitudinal slot or window may be provided, if desired with markings on it. These markings reveal the supply level, respectively the number of doses left.

The propellant-free inhalation device according to the invention can also be provided with a dose counting system, where the counting steps can be derived from the rotation of the dosing means, for example via a gear system provided with numbers or by colour stripes.

In the figs. 3 and 4 cross-sectional views of modified dosing means 3 are shown. In fig. 3 the dosing chambers 4 of the dosing means 3 are flattened in the bottom area and embodied less deep compared to those of the previously described embodiment.

The dosing chambers 4 of the dosing means 3 in fig. 4 show a triangular cross-section which are moulded in relation to the direction of rotation indicated by arrow A.

Moreover the axis 21 of the mouthpiece 5 not necessarily has to stand perpendicularly on the axis of the supply chamber 1 as illustrated in fig. 1. Good results also have been obtained when the angle between the axes 20 and 21 generally lies in the range of 90 to 130°.

CLAIMS

1. Propellant-free inhalation device with a supply of pulverized medical substance in a supply chamber, a manually actuatable metered dosing means (3) in form of a rotatable metering drum having one or more peripheral recesses (dosing chambers (4)) to receive in one position from the supply chamber the dose of the medical substance to be inhaled and to discharge the dose in another position, with a mouthpiece (5), formed at the side of the housing of the inhalation device for active inhalation and with an air channel (6) for distributing the discharged dose in the breathing air flow and with at least one air intake (8) embodied within the housing, characterized by the following features

   - the main axis (21) of the mouthpiece (5) and the axis of the dosing means (3) form an angle in the range of 70 to 110°, preferable 90°;

   - the air channel (6) is led on the level of the dosing means (3) directly to the periphery of the dosing means, offset from the outlet of the supply chamber;

   - the air intake (8) is formed within the attachment area of the mouthpiece (5) and is extended to the periphery of the dosing means (3) in the orifice area the air channel (7).

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2. Inhalation device according to claim 1, characterized in that the dosing means (3) is received in a fixed hollow cylindrical body (7) which has recesses corresponding to the width of the dosing chambers (4) set off on the circumference according to the angular distance of the dosing chambers on the dosing means, said recesses being loceated on the one side in the area of the supply chamber (1) and on the other side in the area where the air channel (6) of the mouthpiece (5) and the air intake (8) discharge into the cylindrical body (7).

3. Inhalation device according to claim 2, characterized in that between the recess associated with the mouthpiece (5) and a wall portion (5a) of the mouthpiece an opening (7b) is formed for the passage of the intaken air directly to the periphery of the dosing means.

4. Inhalation device according to claim 3, characterized in that the opening (7b) is moulded in form of a nozzle.

5. Inhalation device according to one of the claims 1 to 4, characterized in that the cross-sectional shape or area of the air channel (6) in the mouthpiece (5) is substantially constant.

6. Inhalation device according to one of the claims 1 to 5, characterized in that a cover (10) for the mouthpiece (5) is provided, having detent elements (11) to fit into the air intakes (8).

7. Inhalation device according to one of the claims 1 to 6, characterized in that the supply chamber (1) is closed with a lid (1a) having on its inner side a chamber to take up a drying agent.

8. Inhalation device according to one of the claims 1 to 7, characterized in that over the supply chamber (1) a cover (2) may be fitted.

9. Inhalation device according to one of the claims 1 to 8, characterized in that a manually actuatable vibrating mechanism is provided for vibrating the supply of pulverized medical substance.

10. Inhalation device according to claim 8 or 9, characterized in that notches are provided on the cover (2) of the supply chamber (1) and that by a motion relative to the wall of the supply chamber vibrations are created.

11. Inhalation device according to one of the claims 1 to 10, characterized in that the manually actuable rotative drive for the dosing means (3) includes a stepping mechanism which allows only stepwise rotation of the dosing means with a step length corresponding to the peripheral distance of the dosing chambers.

12. Inhalation device according to one of the claims 1 to 11, characterized in that an arrangement is provided allowing a visual monitoring of the supply level.

13. Inhalation device according to claim 8 and 12, characterized in that the supply chamber (1) is manufactured from translucent material and the cover (2) for the supply chamber has a longitudinal slot.

14. Inhalation device according to one of the claims 1 to 13, characterized in that a counting system is provided, for the number of doses removed.

15. Inhalation device according to one of the claims 1 to 14, characterized in that the main axis (21) of the mouthpiece (5) and the main axis (20) of the supply chamber (1) form an angle in the range between 90° to 130°.

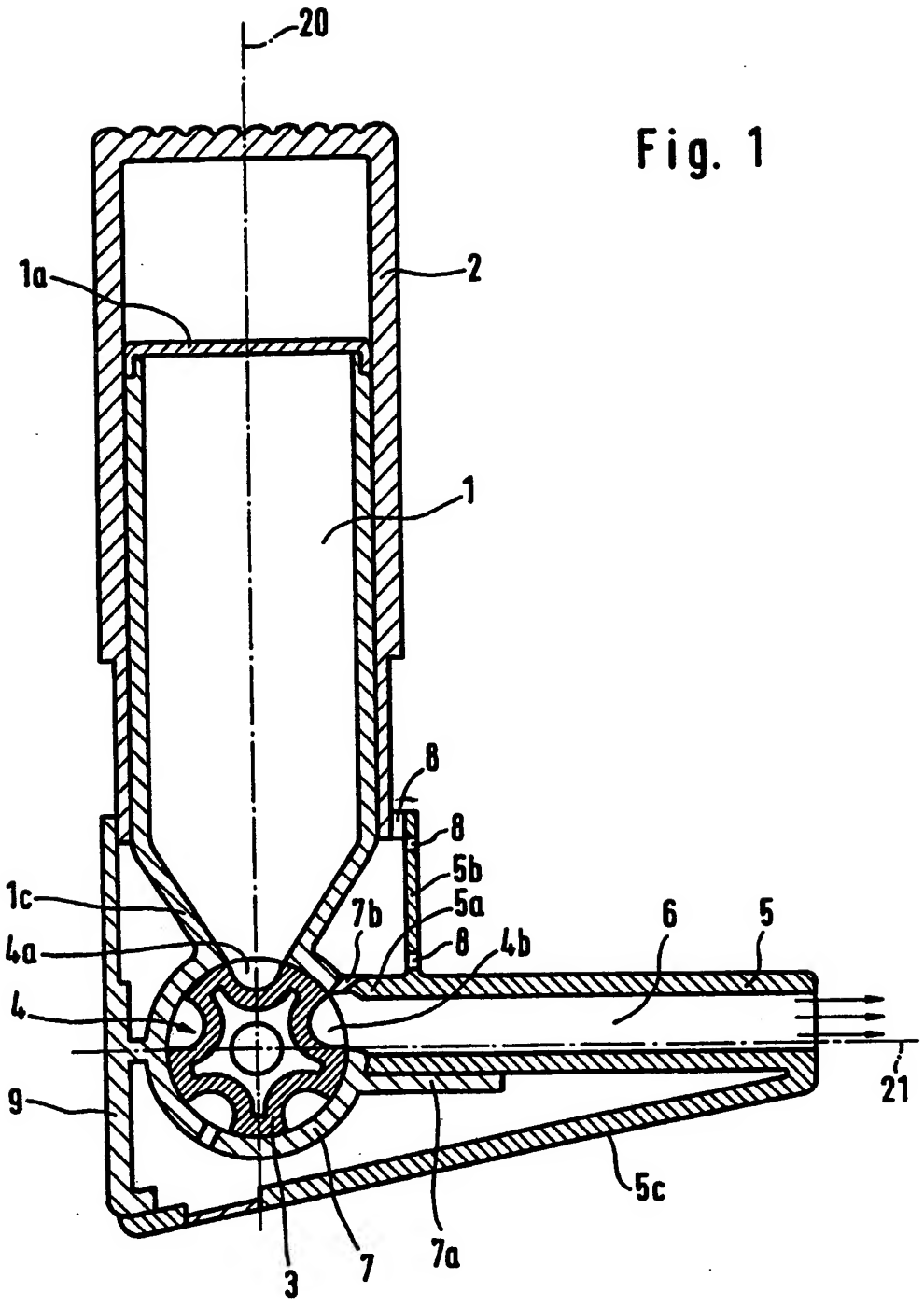
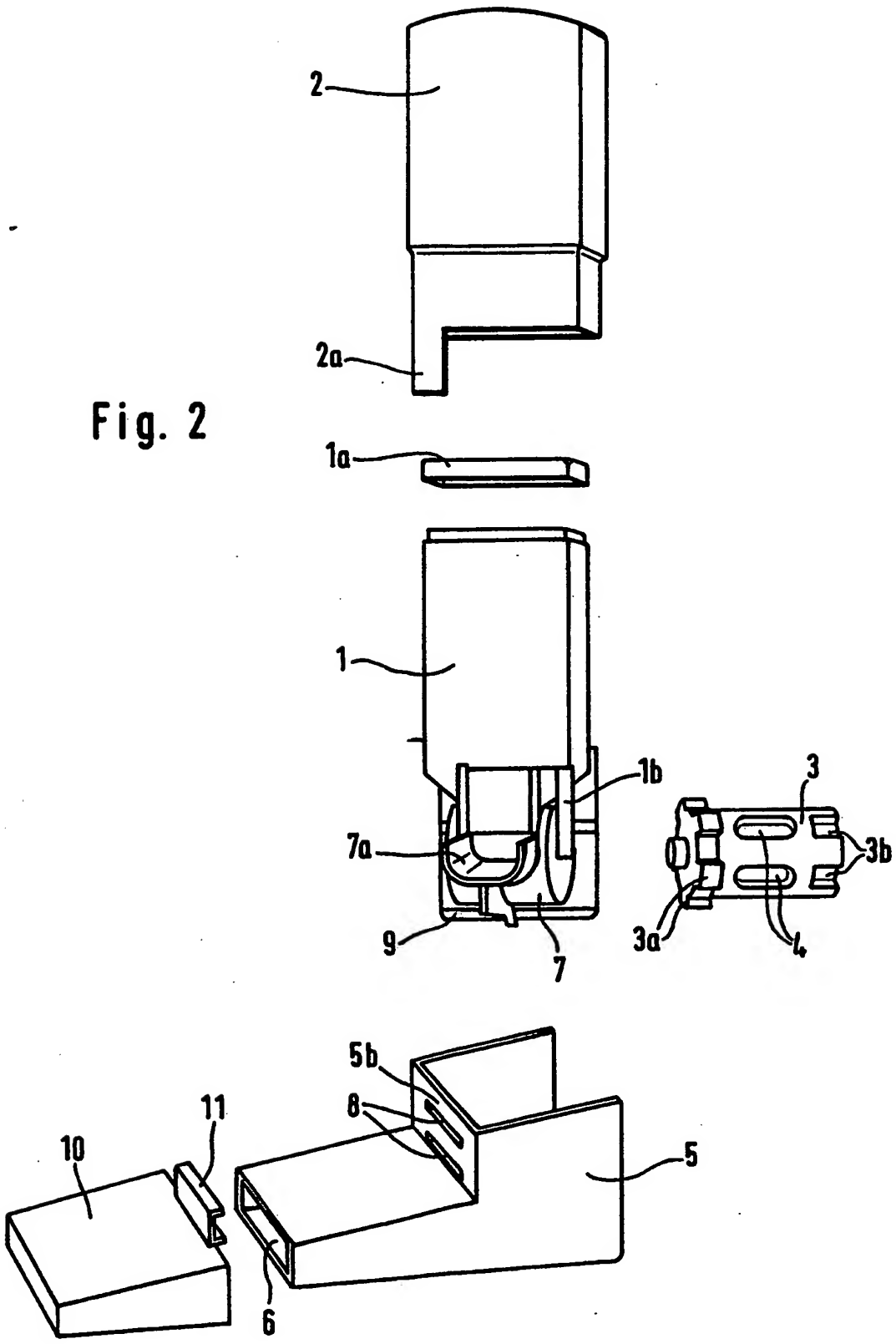


Fig. 1

Fig. 2



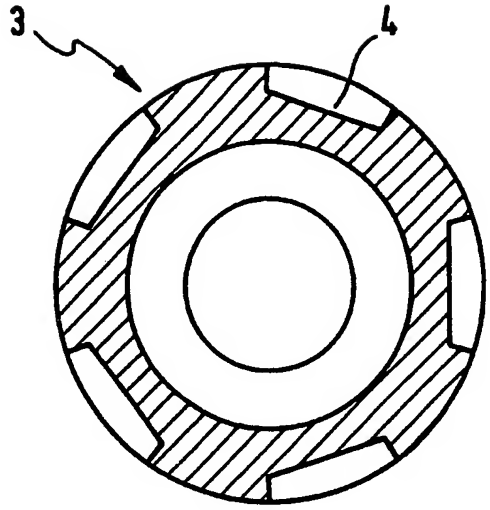


Fig. 3

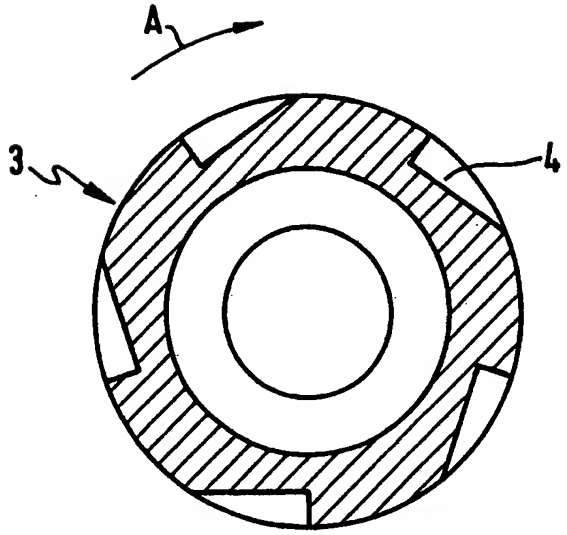


Fig. 4

INTERNATIONAL SEARCH REPORT

PCT/EP 91/02105

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. '5 A61M15/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X A	WO,A,8 201 470 (RIKER LABS) 13 May 1982 see page 19, line 33 - page 22, line 18; figures 5-9	1-5 12,13
A	EP,A,0 079 478 (MILES LABS) 25 May 1983 see the whole document	1,2,13, 15
A	US,A,2 587 215 (F PRIESTLEY) 27 April 1949 see column 4, line 52 - column 5, line 27; figures 7-11	1-4
A	GB,A,2 165 159 (ORION-YHTYMA OY) 9 April 1986 see the whole document & DE,A,3 535 561 22 May 1986 cited in the application	ALL

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
07 FEBRUARY 1992	03.03.92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	VEREECKE A.

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. EP 9102105 SA 52854

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 07/02/92
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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